



Case No. 4380US

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Russell G. Higuchi**) Group Art Unit: 1743
Serial No.: 08/968,208)
Filed: November 12, 1997) Examiner: J. Snay
For: INSTRUMENT FOR) Confirmation Number: 8271
MONITORING NUCLEIC ACID)
AMPLIFICATION)

For hand-delivery to Examiner Snay or
the Group receptionist on or after
October 24, 2003

Information Disclosure Statement

Commissioner for Patents
Washington, DC 20231

Sir:

Applicant submits herewith patents, publications or other information (listed on the attached Substitute Form PTO-1449A) that may be material to the examination of this application and in respect of which there may be a duty of disclosure in accordance with 37 CFR § 1.56. Copies of the cited references are enclosed herewith.

Cite Nos. 21-38 on the attached Substitute Form PTO-1449A correspond to patents, publications or other information not already of record in the above-captioned application that were brought to the attention of the European Patent Office (EPO) by five Opponents and one Intervener opposing a European counterpart to the above-captioned application (European Patent EP 0 872 562) in an Opposition proceeding. Patents, publications or other information cited by the Opponents and Intervener that were already of record in the above-captioned application are not repeated on the Form.

CONTINUED ON ATTACHED SHEET

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CHALMERS

Cite Nos. 43-46 and 48 are copies of the opposition briefs submitted to the EPO by the various Opponents. Cite No. 47 is an Annex (Annex 2) from Cite No. 46. Cite No. 49 is a copy of the Notice of Intervention submitted to the EPO by the Intervener.

Cite No. 47 corresponds to the cover page, title page and pages i-iii, 1, 2, 48-56 and 65 of Eigen et al., "Report on Evolution Research," Department of Biochemical Kinetics, Max Planck Institute fur Biophysikalische Chemie ("Eigen Report"). The cover page and pages i-iii, and 48-56 of this Eigen Report were brought to the attention of the Japanese Patent Office (JPO) in a Japanese counterpart of the instant application (Japanese Patent No. 3136129). The title page and pages i, 1, 2, 53-56 and 65 of this Eigen Report were previously brought to the attention of the Patent Office in a Supplemental Information Disclosure Statement filed July 19, 2001 (Cite No. 19) (these exact same pages were also cited in the opposition brief corresponding to Cite No. 48). The cover page and pages 48, 49 and 53-55 of this Eigen Report are also available from the file history of unrelated European Patent No. EP 0 583 265. Based upon Declarations from the file history of EP 0 583 265 (included herewith as Cite No. 42, along with English translations thereof), Applicant has listed an alleged publication date of April 18-20, 1991 for Cite No. 47 on the Substitute Form PTO-1449A. Applicant notes, however, that its inclusion of a publication date for this reference (or for any other reference) is not an admission that the reference constitutes a printed publication or, if it is a printed publication, that its date of publication was prior to the effective filing date of the above-captioned application. Applicant expressly reserves the right to challenge the availability of this reference to the public and/or its date of availability at a later time.

Cite No. 39 corresponds to pages 1-17 of a dissertation thesis by Hajo Otten. This reference is from the file history of EP 0 583 265. The pages provided are the only pages available from the file history. The publication date of this thesis is unknown. Also provided is an English language translation of the text bridging pages 16-17, beginning with the heading "**2.5 Machinenexperimente.**"

Legal Proceedings Involving Foreign Counterpart Patents

Pursuant to MPEP § 1002.06(c), Applicant notes the following legal proceedings relating to Japanese (Pat. No. 3136129) and European (EP 872562 B) counterparts of the above-captioned application are pending or have been completed:

- (1) PE Corporation (NY) vs. Bio-Rad, Tokyo District Court No. H-14 (wa) 9503
(preliminary injunction action, granted April 14, 2003);
- (2) PE Corporation (NY) vs. Bio-Rad, Tokyo District Court No. H-14 (yo) 22065 (main action, completed April 14, 2003);
- (3) PE Corporation (NY) vs. Bio-Rad, Tokyo High Court Appeal No. H-15 (ne) 2558
(Bio-Rad appeal from item (2), filed in mid-2003);
- (4) Invalidation Appeal No. 2002-35399 filed with the Japanese Patent Office by Bio-Rad on Sept. 20, 2002 (pending);
- (5) Applera vs. Bio-Rad, Düsseldorf Regional Court Case No. 4a O 44/03 filed February 10, 2003 (pending);
- (6) Applera vs. MJ Research, Düsseldorf Regional Court Case No. 4a O 262/02 filed June 20, 2003 (pending); and
- (7) Opposition filed in the European Patent Office by various parties in June, 2003 in connection with EP 872562 B (pending).

Cite No. 50 is an English language translation of the decision of the Tokyo District Court granting the assignee of the above-captioned application a Preliminary Injunction against Bio-Rad, Inc. in Tokyo District Court Case No. H-14 (wa) 9503. The decision summarizes the arguments presented by both parties during the infringement action.

While the information and references disclosed in this Information Disclosure Statement may be “material” pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR § 1.56(a) exists. It is submitted that the Information Disclosure Statement

is in compliance with 37 CFR § 1.98 and MPEP § 609 and the Examiner is respectfully requested to consider the references.

This Information Disclosure Statement accompanies a Request for Continued Examination (“RCE”) under 37 CFR § 1.114. It is therefore being filed before the mailing date of a first Office Action after the filing of the RCE and, consequently, no fees are believed due. However, the Patent Office is authorized to take any required fees from Applied Biosystems Deposit Account No. **01-2213 (Order No. 4380US)**.

Respectfully submitted,

Date: 05.23.2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	08/968,208
				Filing Date	November 12, 1997
				First Named Inventor	Russell G. Higuchi
				Group Art Unit	1743
				Examiner Name	J. Snay
(Use as many sheets as necessary)				Attorney Docket No.	4380US
Sheet	1	of	3		

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Examiner Name	J. Snay
				Attorney Docket No.	4380US

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	26	Advertisement for Perkin Elmer Cetus GeneAmp® PCR System 9600, 1991, BioTechniques 10(2):	
	27	Cardullo et al., 1988, Proc. Natl. Acad. Sci. USA 85:8790-8794	
	28	Derwent Abstract for SU1702312-A1, 1986	
	29	Derwent Abstract for Japanese Patent Application JP63119672-A, 5/24/88 and Patent Abstracts of Japan for Japanese Patent Application JP63119672-A, published 5/24/88	
	30	Eppendorf Product Literature, September 1973	X
	31	FluoroLog-2 Spectrofluorometer Manual (publication date unknown)	
	32	Holland et al., 1991, FASEB 5(4):A261	
	33	Literature Express Circle 245, 1990, BioTechniques 9(5):650	
	34	McCleod, 1990 J. Med. Eng. Tech. 14:60-68	
	35	Murakami et al., 1989, Nucl. Acids Res. 17:5587-5595	
	36	SPEX Catalog (publication date unknown)	
	37	Stufen zum Leben, Piper Verlag, 1987, pp. 5, 193-199	X
	38	Wittwer et al., 1990, Anal. Biochem. 186:328-331	
	39	Dissertation Thesis of Hajo Otten, "Ein Beitrag Zur Durchführung von Kontrollierten Evolutionsexperimenten mit Biologischen Makromolekülen," pp. 1-17 (publication date unknown), English language translation of the text bridging pages 16-17, beginning with the heading "2.5 Maschinenelemente"	X (in part)
	40	Eigen, 1987, "New Concepts for Dealing with the Evolution of Nucleic Acids," Cold Spring Harbor Symposium on Quantitative Biology, Vol. LII, pp. 307-319	
	41	Eigen, allegedly April 18-20, 1991, "Report on Evolution Research," Department of Biochemical Kinetics, Max Planck Institut für Biophysikalische Chemie, cover page, title page and pages i-iii and 48-56	
	42	Declarations of Drs. Manfred Eigen, Ruthild Winkler-Oswatitsch, Björn Lindemann, Andreas Schwienhorst and Rolf Günther from the file history of EP 0 583 265	X

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